

REMARKS

Reconsideration and withdrawal of the claim rejections are requested in view of the amendments and remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-12 and 15 are pending in this application. Claims 1 and 7 are amended; formerly withdrawn claims 14 and 16 are cancelled. Applicants reserve the right to pursue divisional applications to non-elected subject matter.

Support for the amended claims is found throughout the specification. Specifically, support for the fragments of SEQ ID No. 1 recited in part b) of claim 1 can be found on page 47, line 22, of the application. Support for the hybridization conditions recited in part c) of claim 1 can be found on page 21, lines 3-8, of the application. No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH ARE OVERCOME

The Application Contains Adequate Written Description

Claims 1-12 and 15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

It has been established in the prosecution history of this application that there is written description for the nucleotide sequence of SEQ ID No. 1. Parts a) and b) of claim 1 are directed to fragments of SEQ ID No. 1 that are described in the application, and were shown to possess the function of a caryopsis-specific promoter, as required by claim 1 (see the last paragraph on page 47 of the specification). Therefore, written description clearly exists for parts a) and b) of claim 1.

The Office Action contends, on page 3, that “Applicant does not define the hybridization conditions”. This is incorrect; page 21 of the specification defines “stringent hybridization conditions”, and these conditions are now recited in part c) of claim 1. The Office Action further states, on page 4, that “even hybridization conditions of high stringency would not eliminate promoter elements that are not caryopsis specific.” While that statement may or may not be true, such promoter elements are necessarily excluded by the limitation in claim 1 that requires caryopsis specificity. Thus, such argumentation is moot. In view of these considerations, it is clear that written description exists for part c) of claim 1.

Part d) of claim 1 has been amended to recite about 90-95% identity to nucleotides 1-4683 of SEQ ID No. 1. Applicants constructed this claim with specific reference to Example 14 of the “Revised Interim Written Description Guidelines Training Materials”. For the Examiner’s convenience, the relevant portions of Example 14 are set forth below.

Example 14: Product by Function

Specification: The specification exemplifies a protein isolated from liver that catalyzes the reaction of A→B. The isolated protein was sequences and was determined to have the sequence set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

Claim:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A→B.

Analysis:

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3. There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID

NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by members of the genus.

Conclusion: The disclosure meets the requirements of 35 U.S.C. §112 first paragraph as providing adequate written description for the claimed invention.

The facts of the current case exactly mirror those presented in Example 14. Rather than enzymatic activity, the molecule of the instant invention has tissue-specific promoter activity. The specification contemplates variants of the disclosed molecule of Seq ID No. 1, and states, on page 15, that “naturally occurring variants and also artificial nucleotide sequences, for example those obtained by mutagenesis or chemical synthesis”, routine procedures in the art, can be used in the invention. The paragraph beginning on page 16, line 8, of the application teaches how to determine caryopsis specificity, *i.e.*, the assay for detecting activity of the molecule, analogous to the enzymatic assay discussed above in Example 14.

As is true of the sample claim in Example 14, so too does claim 1 of the instant application recite a particular sequence, a percent identity, and a functional requirement. In Example 14, a single species is disclosed, whereas, in the current application, fragments of the disclosed species have also demonstrated functionality in the assays taught by the Applicants. Reduction to practice of the disclosed species has been shown, and all of the variants encompassed in part d) of claim 1 must possess the specified activity and must have at least 90-95% identity to the reference sequence, nucleotides 1-4683 of Seq ID No. 1.

Therefore, as posited in Example 14, a single species disclosed is representative of the genus because all members have at least 90-95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 90-95% identical variants of nucleotides 1-4683 of Seq ID No. 1 which are capable of the specified promoter activity. The example makes **no** mention of the requirement that specific

substitutions, deletions, insertions or additions must be taught. As such, part d) of claim 1 directly corresponds with the criteria set forth in the USPTO's own guidelines, summarized above. Therefore, written description clearly exists for claim 1d).

The Office Action raises a concern that the characteristics of the nucleic acid molecule of claim 1 are recited in the alternative. It should be clear that the claimed nucleic acid of claim 1 need not possess every characteristic recited in claim 1; it simply must have the sequence of nucleotides 1-4683 of Seq ID No. 1, or be structurally related to that sequence, as specified in parts b)-d) of claim 1, and it must have the function of a caryopsis-specific promoter. It would not make sense to recite the characteristics of claim 1 with an "and" conjunction, rather than an "or" conjunction, because, for example, a nucleic acid meeting the description in part b) need not have the entire sequence as recited in part a). Therefore, reciting the parts of claim 1 in the alternative is correct, and does not render the claim inadequately described.

The Claims Are Enabled

Claims 1-12 and 15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The application describes how to obtain the promoter of Seq ID No. 1, how to produce various fragments of Seq ID No. 1, and how to test the fragments to determine whether they are functional.

There would be no undue experimentation on the part of the skilled artisan to isolate a nucleic acid molecule that has the nucleotide sequence of Seq ID No. 1, or a functional portion thereof, or that has approximately 90-95% sequence identity to Seq ID No. 1. Further, procedures for identifying, by structural characteristics, a nucleic acid molecule having approximately 90-95% identity to Seq ID No. 1 are standard in the art. There is no reason to expect that one of skill in the art could not identify a member of the claimed genus based on its structural and functional characteristics. Non-functional embodiments are excluded by the functional requirement stated in claim 1.

The Examiner is respectfully reminded that the standard for enablement precludes undue experimentation, not any experimentation at all. It is well within the skill of one in the art to use the methods taught in the application to arrive at a nucleic acid molecule having approximately 90-95% sequence identity to nucleotides 1-4683 of Seq ID No. 1. Modifying nucleic acid sequences is standard in the art, as is determining tissue-specific promoter activity.

Given that several fragments of Seq ID No. 1 have demonstrated activity, it is unreasonable to assert that changes of up to 10% in the sequence of the full length promoter would result in a nucleic acid that is unpredictably functional. For example, a nucleic acid sequence consisting of only 612 nucleotides of Seq ID No. 1 (positions 4071-4683), corresponding to only 12% of the full length sequence, retained the function of a caryopsis-specific promoter. It is nonsensical to maintain that a sequence having 90-95% identity to the sequence claimed in part a) of claim 1 would not be predictably functional, given the fact that a sequence having only 12% identity is. While it is possible that some small number of variants encompassed by claim 1d) might not have caryopsis-specific promoter activity, it is submitted that the number would be insignificant, compared with the vast number of nucleic acid molecules having 90-95% sequence identity to nucleotides 1-4683 of Seq ID No. 1 that would be functional.

The claims are in compliance with the first paragraph of §112, and reconsideration and withdrawal of the rejections thereunder are requested.

III. THE REJECTION UNDER 35 U.S.C. §112, 2ND PARAGRAPH IS OVERCOME

Claims 1-12 and 15 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claim 1 has been amended such that it recites specific hybridization conditions, obviating the rejection. Reconsideration and withdrawal are requested.

IV. THE REJECTION UNDER 35 U.S.C. §102 IS OVERCOME

Claims 1-12 and 15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Robert *et al.* The rejection is traversed.

Robert *et al.* describe a glutenin gene from wheat with tissue-specific expression in tobacco. Applicants reiterate that the promoter sequence used in Robert *et al.* is not related to the promoter sequences claimed in the present invention, as is evident from comparison of the sequence of Robert *et al.* with that of the current invention, which shows only 48% identity between the two. Obviously, the sequence of Robert *et al.* does not meet the limitations of parts a), b) or d) of claim 1. Moreover, the hybridization conditions recited in part c) of claim 1 would not produce the promoter sequence used by Robert *et al.* because the similarity between it and the nucleic acid sequence of part a) are too low to hybridize under the stringent conditions required by the claim language. Therefore, Robert *et al.* cannot anticipate claims 1-12 and 15, and reconsideration and withdrawal of the rejections under 35 U.S.C. §102 are requested.

CONCLUSION

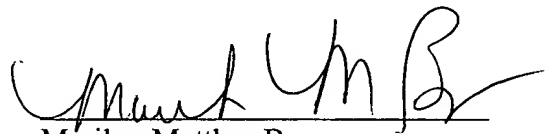
Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The Examiner is invited to contact the Applicants' representative if there are issues that could be resolved telephonically, leading to allowance of the application.

Alternatively, consideration and entry of this paper is requested, as it places this application into better condition for purposes of appeal. A Notice of Appeal, in triplicate, together with the required fee, is filed concurrently herewith.

Respectfully submitted,

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